K102408

510(k) Summary

DEC 27 2010

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: Mar. 18, 2010

1. Company and Correspondent making the submission:

Name – DRGEM Corporation
Address – 7th FL, Dongil Techno-town 1st, 826, Guro-dong, Guro-gu,
Seoul, Republic of Korea, 152-050
Telephone – +82-2-869-8566
Fax – +82-2-869-8567
Contact – Mr. Ki-Nam Yang
Internet – http://www.drgem.co.kr/

2. Device :

Trade/proprietary name	: DIAMOND-5A,6A,8A
Common Name	: Digital Diagnostic X-ray System
Classification Name	: System, x-ray, stationary

3. Predicate Device :

Manufacturer	: Sedecal, Inc.
Device	: Sedecal X-Plus LP Plus Digital
510(k) Number	: K090238 (Decision Date - Feb. 27. 2009)

4. Classifications Names & Citations :

21CFR 872.1680, KPR, System, x-ray, stationary, Class2

5. Description :

5.1 General

The digital X-ray imaging system consists of a high voltage (HV) generator, a tube

support unit, an X-ray beam limiting device, a wall stand unit, a bucky table unit, a detector, operating software, and a tube, operates on a high-frequency inverter method, and is primarily used in a hospital for diagnosis of diseases in skeletal, respiratory and urinary systems.

5.2 Product features

Rated voltage from external power supply is introduced into the X-ray control device, and the tube voltage, tube current and time are set up. When an X-ray radiation command is given, the preset voltage is applied to the primary side of the high voltage generator and a high voltage to produce X-ray is generated from the secondary side.

When this high voltage is applied to the X-ray tube, it strikes substance named target and X-ray is generated. This X-ray passes part of a human body to be diagnosed.

Electric charges are collected by electrodes located at each pixel, and outputted to the image processing unit through the thin film transistor (TFT) array. Amplification and digital data conversion take place in the image processing unit, and the data that has been transmitted to the workstation (image processing computer) through a cable is stored in medical standard DICOM files by operating software. Stored images are used for image analysis after transmitted to the picture archiving and communication system (PACS) by operating software.

5 Indication for use :

The DIAMOND-5A,6A,8A Digital X-ray Imaging System is indicated for use in generating radiographic images of human anatomy. This device is not intended for mammographic applications.

6 Comparison with predicate device :

DRGEM Corporation, believes that the DIAMOND-5A,6A,8A is substantially equivalent to the Sedecal X-Plus LP Plus Digital of Sedecal, Inc..

7 Safety, EMC and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard EN/IEC 60601-1, EN/IEC 60601-1-1, EN/IEC 60601-1-3, EN/IEC 60601-

2-7, EN/IEC 60601-2-28 and EN/IEC 60601-2-32 was performed, and EMC testing was conducted in accordance with standard EN/IEC 60601-1-2(2001). All test results were satisfactory.

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification DRGEM Corporation concludes that The DIAMOND-5A,6A,8A is safe and effective and substantially equivalent to predicate devices as described herein.

10. DRGEM Corporation will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

DRGEM Corporation
% Mr. Charlie Mack
International Regulatory Consultants
77325 Joyce Way
ECHO OR 97826

DEC 27 2010

Re: K102408
Trade/Device Name: Digital Diagnostic X-ray System / DIAMOND-5A, 6A, 8A
Regulation Number: 21 CFR 892.1630
Regulation Name: Electrostatic x-ray imaging system
Regulatory Class: II
Product Code: KPR
Dated: November 13, 2010
Received: November 22, 2010

Dear Mr. Rodenberger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

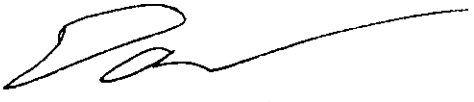
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

DEC 27 2010

510(k) Number(if known): K102408

Device Name: Digital Diagnostic X-ray System / DIAMOND-5A,6A,8A

Indications for Use:

The DIAMOND-5A,6A,8A Digital Diagnostic X-ray System is indicated for use in generating radiographic images of human anatomy. This device is not intended for mammographic applications.

Prescription Use ✓ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K102408